510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k041696

B. Purpose for Submission:

New Device

C. Manufacturer and Instrument Name:

American Bio Medica Corporation

D. Type of Test or Tests Performed:

The Rapid Reader System is a reader designed to capture, document and archive ABMC Drug of Abuse qualitative test results using Rapid Drug Screen, Rapid One, and Rapid TEC Multiple Dip Stick.

E. System Descriptions:

1. Devise Description:

   The Rapid Reader System utilizes a digital camera and software algorithm to detect and read the presence and/or absence of the test and control lines of American Bio Medica Corporation's urine drugs of abuse screening assays. These assays include Rapid Drug Screen, Rapid One, or Rapid TEC drug of abuse test for the simultaneous detection of up to 10 drugs of abuse in human urine.

2. Principles of Operation:

   Reflected density measurement

3. Modes of Operation:

   The Rapid Reader is an instrument that evaluates the reflection or optical density, of a biochemical reaction compared to the environmental background of the measurement sample. Measurement values of the Rapid Reader are correlated linearly to the reflected density measurements of the control function.

4. Specimen Identification:

   Urine

5. Specimen Sampling and Handling:

   Fresh urine samples should be used. Urine samples do not require any special handling or pretreatment. Urine samples should be tested as soon as possible after collection. However, urine specimens may be refrigerated at 2 ^{o} to 8 ^{o}C for 2 days or frozen at -20 ^{o}C for longer periods.

6. Calibration:

   The assessment of qualitative measurements is achieved by creating an algorithm, or Master Function, in the Reader's software. This Master Function is then used to interpret the image received from the CCD camera's scans of the drug test. The Reader's software then outputs to the computer screen a test result reported as "POSITIVE", "NEGATIVE", or "INVALID".

7. Quality Control:

   The control card is provided by ABMC to evaluate the performance of the Rapid Reader. Frequency of measurements of the control card should correspond to local practices to quality control the system.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X_____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CFR 862.2560, Fluorometer for clinical use; 21 CFR 862.3100, Amphetamine Test System; 21 CFR 862.3150, Barbiturate Test System; 21 CFR 862.3170, Benzodiazepine Test System; 21 CFR 862.3870, Cannabinoids Test System; 21 CFR 862.3250, Cocaine and Cocaine Metabolites Test System; 21 CFR 862.3610, Methamphetamine Test System; 21 CFR 862.3620, Methadone Test System; 21 CFR 862.3640, Morphine Test System

2. Classification:

   Class I; Class II

3 Product code:

KHO; DKZ; DIS; JXM; LDJ; DIO; DJC; DJR; DPK; DJG; LCM; JXN; LFG

4. Panel:

Clinical Chemistry (75); Clinical Toxicology (91)

G. Intended Use:

1. Indication(s) for Use:

The Rapid Reader System is designed to automatically read, capture, document, and archive ABMC's Rapid Drug Screen, Rapid One, and Rapid TEC screening immunoassays ("ABMC tests"). The Rapid Reader is used to obtain qualitative results and is intended for professional and point of care use only. It is not intended for over the counter sale to non-professionals. The Rapid Reader, combined with ABMC tests, is simplified qualitative screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e., gas-chromatography/mass spectrometry (GC/MS) or HPLC.

After having performed the ABMC tests (according to instructions for use of each ABMC tests) the ABMC test is inserted into the device holder of the Rapid Reader. The Rapid Reader scan the device, and the results are displayed.

The performance characteristics of the device have not been determined fot use as point of care. This statement of intended use will be included in the operation manual.

2. Special Conditions for Use Statement(s):

None

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

Triage Meter, k973547

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended Use	Determines qualitative positive or negative result from drug of abuse immunoassay screens.	Determines qualitative positive or negative result from drug of abuse immunoassay screens.
Measurement method	Scan the sample	Scan the sample
Output	Outputs "positive" or "Negative" result on paper printout	Outputs "positive" or "Negative" result on paper printout

I. Special Control/Guidance Document Referenced (if applicable):

DIN ES ISO 9001:2000 Quality Management Systems

98/79/EC Directive on in vitro diagnostic medical device

89/336/EWG Electromagnetic compatibility

73/23/EWG Low voltage guideline

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:
The Rapid Reader interpretation of results was compared to manual interpretation (human eye interpretation) of ABMC's Rapid One devices. Certified negative and positive controls for each of the 14 drugs of abuse were tested using ABMC's Rapid One assay by three untrained professionals for each of 14 drugs. The results were then interpreted both manually and using two ARMC Rapid Readers by each of the operators. The results are summarized as following:

Amphetamine

	Rapid Reader	
GC/MS	+	-
+	48	0
-	3	45
Manual		
+	51	9
-	0	36

Agreement of Rapid Reader with reference method – 97%

Barbiturates

	Rapid Reader	
GC/MS	+	-
+	48	0
-	0	48
Manual		
+	48	9
-	0	39

Agreement of Rapid Reader with reference method – 100%

Benzodiazepines

	Rapid Reader	
GC/MS	+	-
+	48	0
-	15	33
Manual		
+	63	8
-	0	25

Agreement of Rapid Reader with reference method – 84%

Cocaine

	Rapid Reader	
GC/MS	+	-
+	48	0
-	1	47
Manual		
+	49	14
-	0	33

Agreement of Rapid Reader with reference method – 99%

Methadone

	Rapid Reader	
GC/MS	+	-
+	48	0
-	12	36
Manual		
+	60	6
-	0	30

Agreement of Rapid Reader with reference method – 87%

MDMA

	Rapid Reader	
GC/MS	+	-
+	48	0
-	8	40
Manual		
+	56	7
-	0	33

Agreement of Rapid Reader with reference method – 92%

Methamphetamines

	Rapid Reader	
GC/MS	+	-
+	48	0
-	2	46
Manual		
+	50	11
-	0	35

Agreement of Rapid Reader with reference method – 98%

Opiates 300

	Rapid Reader	
GC/MS	+	-
+	48	0
-	14	34
Manual		
+	62	5
-	0	29

Agreement of Rapid Reader with reference method – 85%

Opiates 2000

	Rapid Reader	
GC/MS	+	-
+	48	0
-	9	39
Manual		
+	57	4
-	0	35

Agreement of Rapid Reader with reference method – 91%

Oxycodone

	Rapid Reader	
GC/MS	+	-
+	48	0
-	4	44
Manual		
+	52	6
-	0	38

Agreement of Rapid Reader with reference method – 96%

Phencyclidine

	Rapid Reader	
GC/MS	+	-
+	48	0
-	3	45
Manual		
+	51	6
-	0	39

Agreement of Rapid Reader with reference method – 97%

Propoxyphene

	Rapid Reader	
GC/MS	+	-
+	48	0
-	6	42
Manual		
+	54	6
-	0	36

Agreement of Rapid Reader with reference method – 94%

THC

	Rapid Reader	
GC/MS	+	-
+	48	0
-	0	48
Manual		
+	48	0
-	0	48

Agreement of Rapid Reader with reference method – 100%

Tricyclic Antidepressants (TCA)

	Rapid Reader	
GC/MS	+	-
+	48	0
-	7	41
Manual		
+	55	8
-	0	33

Agreement of Rapid Reader with reference method – 93%

Concentration	Rapid Reader % Agreement	Manual Read % Agreement
Drug Free	100%	100%
50% of Cutoff	75%	44%
125% of Cutoff	100%	100%
150% of Cutoff	100%	100%

Overall agreement of the Rapid Reader with reference method – 94%

b. Precision/Reproducibility:

The tests described in accuracy section above were the control samples that were tested in triplicate and read by three different operators on two readers over a period of time. The results listed above are adequate to support the precision performance of the Rapid Reader.

c. Linearity:

Not applicable

d. Carryover:

Not applicable

e. Interfering Substances:

The interfering substances information in the previous 510(k) submissions from the same applicant for Rapid Drug Screen and Rapid One, Rapid Drug Rapid One Propoxyphene, Rapid One ECATASY, Rapid One Methadone, Rapid One OXY, and Rap Tec Multiple Dip Stick are applicable for this submission.

2. Other Supportive Instrument Performance Data Not Covered Above:

   Measurement of Reflective Density using American Bio Medica Corporation Rapid Reader

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.